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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/200,657	11/25/1998	MICH B. HEIN	TSRI-184.2CO	9640
7590 07/01/2004			EXAMINER	
FOLEY & LARDNER			COLLINS, CYNTHIA E	
BARRY S. WILSON			ART UNIT	
P.O. BOX 80278			PAPER NUMBER	
SAN DIEGO, CA 92138-0278			1638	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/200,657

Applicant(s)

HEIN ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 79,81-85,87-90 and 93-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 79,81-85,87-90 and 93-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1003</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2004 has been entered.

Claims 1-78, 80, 86, 91-92 and 96-99 are cancelled.

Claims 79, 81-84 and 87-89 are presently amended.

Claims 79, 81-85, 87-90 and 93-95 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449, filed October 31, 2003 is attached to the instant Office action.

### ***Claim Objections***

Claim 83 objected to because of the following informalities: the word "polypeptide" is misspelled in line 13. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 79 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 79 is directed to the plant of claim 83 wherein said product comprising a single immunoglobulin polypeptide (containing an immunoglobulin heavy chain polypeptide) is present at a level of at least 56 ng/mg of total protein in extracts of said plants. The limitation "is present at a level of at least 56 ng/mg of total protein in extracts of said plants" in reference to a product comprising a single immunoglobulin polypeptide containing an immunoglobulin heavy chain polypeptide does not find support in the specification as originally filed, and thus it constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 83, and claims 79, 81-82, 84-85, 87-90 and 93-95 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 83 recites the limitation "said single polypeptide product" in line 5, in lines 6-7, and in line 13. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claim be amended to recite either "said immunoglobulin product" or "said single immunoglobulin polypeptide" in order to overcome the rejection.

Claim 83 also recites the limitation " immunoglobulin single polypeptide product encoded by said nucleotide sequence" in lines 11-12. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claim be amended to recite "immunoglobulin product encoded by said nucleotide sequence" in order to overcome the rejection.

Claim 83 additionally recites the limitation " said polypeptide product" in lines 12-13. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claim be amended to recite either "said immunoglobulin product" or "said single immunoglobulin polypeptide" in order to overcome the rejection.

Claim 84, and claim 85 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 84 recites the limitation "wherein said product comprising a single immunoglobulin polypeptide associates with a polypeptide to form a multimer". The identity of the multimer formed is unclear, as the claim does not specify the identity of the polypeptide with which the product comprising a single immunoglobulin polypeptide associates.

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Claim 88 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 88 is indefinite in the recitation of “wherein said product comprising a single immunoglobulin polypeptide comprises a paratope”, since a paratope requires the presence of an immunoglobulin heavy chain as well as an immunoglobulin light chain, and since the instant application was restricted to plant cells containing nucleotide sequences encoding heavy chain immunoglobulin polypeptides only.

Claim 83, and claims 79, 81-82, 84-85, 87-90 and 93-95 dependent thereon, remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “wherein said plant cells do not contain nucleic acid encoding said light chain”, for the reasons of record set forth in the office action mailed October 27, 2003.

Applicant's arguments filed March 29, 2004, have been fully considered but they are not persuasive.

Applicants respectfully submit that the Examiner has not indicated any basis for a lack of clarity. Applicants maintain that “said light chain” clearly and unambiguously refers back to the light chain from the cell that expresses a heavy and a light chain recited earlier in the claim.

(reply page 7)

The rejection is maintained because it is unclear whether the plant cells do not contain any nucleic acid encoding a light chain polypeptide, or whether the plant cells do not contain only the nucleic acid encoding the specific light chain from the particular antigen-specific immunoglobulin that the heavy chain is obtained from. In this regard it is noted that the instant

application was restricted to plant cells containing nucleotide sequences encoding heavy chain polypeptides only. The limitation "wherein said plant cells do not contain nucleic acid encoding said light chain" was added to claim 83 in the amendment filed April 2, 2003. Applicants' remarks at page 6 of this amendment indicated that "The current amendments make clear that the plant cells do not contain nucleic acid encoding the light chain. Thus, claim 83 covers transgenic plants which separately express the heavy chain of an antigen-specific immunoglobulin." Yet the recitation of "said" light chain allows for a claim interpretation in which the plant cells may comprise nucleic acids encoding light chain polypeptides other than the specific light chain polypeptide from the particular antigen-specific immunoglobulin that the heavy chain is obtained from. It is suggested that the claim be amended to recite "a" rather than "said" in order to overcome the rejection.

***Remarks***

Claims 79, 81-85, 87-90 and 93-95 are rejected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

*Cynthia Collins* 6/24/04